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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/577,258 05/22/00 WEINER

R P-8769.00

EXAMINER

QM12/0302

MEDTRONIC, INC.
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BIRD, J

ART UNIT

PAPER NUMBER

3762

DATE MAILED:

03/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/577,258	Applicant(s) WEINER, RICHARD L.	
	Examiner John M. Bird	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 20) <input type="checkbox"/> Other: |

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DETAILED ACTION

Information Disclosure Statement

1. Two reference citations from the information disclosure statement filed November 24, 2000 fail to comply with the provisions of 37 CFR 1.98 and MPEP § 609 because they fail to include the month and year of publication. The information disclosure statement has been placed in the application file, but two of the references have not been considered as to the merits.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

2. Claims 3-5 are objected to because of the following informalities: In claim 3, delete one of the two adjacent phrases "step of". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 34, 40 and 46 "a peripheral nerve" is vague because it is unclear if this is the same nerve mentioned in the preamble (it is suggested to use --the peripheral nerve--).

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In claim 29 "an occipital nerve" is vague because it is unclear if this is the same nerve mentioned in the preamble (it is suggested to use --the occipital nerve--).

In claims 5 and 8, "the detected level of pain" lacks an antecedent basis; although there is an antecedent nerve causing pain, there is no antecedent basis for a detected level of pain.

In claims 17 and 18, "to evaluate" and "to develop" render the claim indefinite because by using infinitives it is unclear whether evaluating and developing are further limiting method steps (it is suggested to list these as additional steps by using gerunds, such as --evaluating-- and --developing--).

In claims 40 and 46, the preamble is inconsistent with the claim body because the preamble claims a method to treat "neuralgias" a specific type of pain, while the claim body refers only to a nerve causing "pain".

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Liss et al. (4,586,509). Liss discloses a method for electronically stimulating a peripheral nerve to alleviate pain in which the area of pain is first palpated to identify the problem area (column 4, lines 52-58). The elements of the claim are met by the reference.

8. Claims 1-3, 14-19, 21-22, 25-27, 34-36, 38-42, 44-48, and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Tannenbaum (4,223,986). Tannenbaum discloses a method for controlling pain by electrical stimulation of a peripheral nerve which uses more than one lead (column 2, lines 7-19) and a test lead that is stimulated to evaluate the lead position and stimulation parameters (column 4, lines 36-40). With respect to claim 19, the method included assessing a patient's pain intensity, duration, and frequency as well as other factors after treatment (column 5, lines 4-19). It is inherent that this profile included some sort of verbal feedback from the patients. With respect to claims 21-22, the electrical stimulation pulse had a frequency from 50-150 Hz and a pulse width of 68-740 microseconds. With respect to claims 25-27, 38-39, 44, and 50-51, a screening lead is used (column 3, lines 22-27) before a permanent lead is subcutaneously placed across the peripheral nerve (column 6, lines 19-38). With respect to claims 34-36, 38-42, 44-48, and 50-51, the method is used with a relevant nerve that is experiencing pain (column 2, lines 17-18). The elements of the claim are met by the reference.

9. Claims 1-8, 10-13, 29-38, 40-44, and 46-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Alo et al. (6,104,957). Alo discloses a method of managing chronic pain by subcutaneously placing a lead near or across a peripheral nerve, including placing the lead in the fascia superior to the peripheral nerve (column 5, lines 2-27 and Fig. 3). With respect to claims 5, 8, 31, 34, 40, and 46 it is inherent that the nerve stimulated is the nerve proximal to the level

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of detected pain. With respect to claims 10-12, the lead is implanted with a Touhy-like insertion needle and is passed through the needle (column 4, lines 46-55) into a position above the peripheral nerve (Fig. 3). It is inherent that the Touhy-like insertion needle, which is also discussed in this application's specification, is removed after insertion. With respect to claim 13, the insertion needle is curved to enable it to be inserted into the patient's body at a position superior to the peripheral nerve. With respect to claims 29-33, it is inherent that the nerve stimulated is the occipital nerve when the lead is inserted at the C1 vertebral position (column 5, line 25). With respect to claims 34-38, 40-44, and 46-50, the nerve stimulated by the disclosed method can be any nerve within the cervical, cervicobrachial, thoracic, or lumbosacral region (column 5, lines 16-28). The elements of the claims are met by the reference.

10. Claims 1-3, 6, 14-22, 34-38, 40-44, and 46-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Law et al. (5,938,690). Law discloses a pain management method in which electrical energy is subcutaneously applied to spinal nerve roots or nerve bundles (column 1, lines 19-28), thus to the nerves peripheral to the spinal cord. It is inherent that the lead comes into contact with the nerve and is therefore placed across the nerve. With respect to claim 14, the method can include multiple leads (column 6, lines 33-37). With respect to claims 14-20, a test stimulation mode is used wherein a user changes the amplitude of the electrical stimulation of a screening device, a patient verbally indicates the paresthesia coverage, and a computer evaluates the effectiveness of the lead position and suggests any changes, including a stimulation parameter setting (column 8, line 35- column 9, line 20). With respect to claim 20, the electrical signal can be from 0 to 12 Volts (Figs. 7-8). With respect to claims 21-22, Law's specification incorporates by reference Borkan (4,612,934), which describes a prior art system for managing

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pain (column 1, lines 47-49). Borkan discloses a tissue stimulator in which the stimulation pulses can be anywhere from 0 to 1500 Hz (column 7, lines 54-56) with a pulse width of 25 to 1000 microseconds (column 8, lines 9-10). The elements of the claims are met by the reference.

11. Claim 23 is rejected under 35 U.S.C. 102(e) as being anticipated by Law, or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Law as applied to claim 1 above. Law discloses a method of stimulating a peripheral nerve that uses an implantable pulse generator (Fig. 1). The elements of the claim are met by the reference.

In the alternative, it is well known in the art to use method for stimulating a peripheral nerve in which an implantable pulse generator is connected to a stimulation lead. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of stimulating a peripheral nerve taught by Law with an implantable pulse generator, since such a modification is well known in the art. (In addition, the specification discloses that it is well known to implant a pulse connected to a lead (page 11, lines 13-16).)

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Law. It is well known in the art it is well known in the art to use method for stimulating a peripheral nerve in which an implantable RF system receiver is connected to a stimulation lead. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of stimulating a peripheral nerve taught by Law with an RF system receiver, since such a modification is well known in the art. (In addition, the specification discloses that it is well known to implant a pulse connected to a lead (page 11, lines 13-16).)

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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Bird whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday - Friday 8:30 AM -5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JB

JB
February 26, 2001

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GEORGE R. EVANISKO
PRIMARY EXAMINER

2/26/1